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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/641,528 | 08/15/2000 | Allesandro Sette | 18623-016100US | 6891 |

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EXAMINER

HILL, MYRON G

ART UNIT PAPER NUMBER

1648

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/641,528

Applicant(s)

SETTE ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1- 37 is/are pending in the application.
- 4a) Of the above claim(s) 11- 13, 25- 27, and 34- 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1- 10, 14- 24, 28 and 29 is/are allowed.
- 6) ☒ Claim(s) 30- 33, and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

This action is on claims 1- 10, 14- 24, 28- 33, and 37.

Claim 37 was omitted from the last Office Action as noted by Applicant. It is treated in this action and is in the group of claims 30- 33.

Rejections Withdrawn

Claims 1- 10, 14- 24, and 29 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear in claim 1 what the metes and bounds of the size of "epitope" is. The term is defined (on page 10, starting from line 5) as to include protein or peptide molecules larger than the epitope of the invention. This reads on products of nature. On page 13, lines 9- 29 the term peptide is defined as "limited" when it has 100% homology to natural sequences but it is not clear how it is limited to be smaller or different. The claims are considered to read on any sequence that comprises the epitope (elected SEQ ID No: 31040).

In claims 8 and 9, the terms "heteropolymer" and "homopolymer" are not defined in the specification and it is not clear the metes and bounds of the terms.

Applicant has amended the claims and pointed out relevant parts of the specification.

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The arguments have been fully considered and found persuasive in part. The rejection of claim 30 remains and is listed below.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1- 10, 14- 24 and 28- 33 were rejected under 35 U.S.C. 103(a) as being obvious over Kubo (US Patent) and NCBI Sequence listing.

Applicant's argument that the art does not teach or suggest the peptide of the claimed invention is persuasive and the rejection is withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 30 it is not clear what the unit dose is.

Applicant explains that unit dose is defined in the art.

The arguments have been fully considered and are not found persuasive.

Unit dose implies some specific amount and none is given. A "unit dose" is not a fixed amount but varies for each composition and must be determined for each type of use. The unit dose for this specific peptide has not been determined. The claim also still reads on full length peptide because it uses the term "comprises". The rejection is maintained.

Claims 30- 33 and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for stimulating CTL responses *in vitro*, does not reasonably provide enablement for vaccines. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant has amended the preamble to remove the word vaccine.

The arguments have been fully considered and not found persuasive.

The composition is still as claimed previously. The composition still comprises a peptide, a pharmaceutical excipient and is given in a unit dose. These limitations still imply the intended use of vaccine. There is no specified unit dose and there is no recited intended use for the unit dose. It is not clear what the unit dose of the pharmaceutical composition does or what dose is required to achieve the desired result.

The rejection is maintained.

Conclusion

Claims 1- 10, 14- 24, 28, and 29 are free of the prior art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

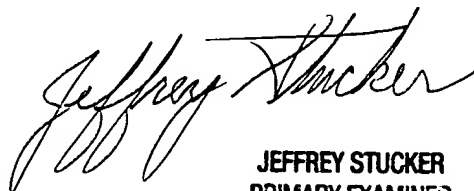
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Myron G. Hill
Patent Examiner
January 7, 2004



JEFFREY STUCKER
PRIMARY EXAMINER